DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Biomet Manufacturing Corporation
Ms. Victoria Scheitlin
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46582

November 13, 2014

Re: K142658
Trade/Device Name: Biomet Headless Compression and Twist-Off Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 9, 2014
Received: September 18, 2014

Dear Ms. Scheitlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142658

Device Name
Biomet Headless Compression and Twist-Off Screws

Indications for Use *(Describe)*
The Biomet Headless Compression Screws and Twist-Off Screws are indicated for fixation of bone fractures, fusion of a joint (arthrodesis) or bone reconstruction (osteotomy) of the mid-foot bones, metatarsal and phalanges of the foot or the phalanges, metacarpals and carpals of the hand. In the foot, these include procedures to correct Hallux Valgus (bunions), Hallux Varus and Hallux Rigidus, Hammer toe, Claw toe and Mallet toe.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the FRS and Twist-Off Screws 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:
Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact:
Victoria Scheitlin
Regulatory Affairs Specialist

Date:
November 12, 2014

Subject Device:
Trade Name: Biomet Headless Compression and Twist-Off Screws

Common Name: Screw, Fixation, Bone
Classification Name:

- HWC– Smooth or Threaded Metallic Bone Fixation Fastener (21 CFR 888.3040)

Legally marketed devices to which substantial equivalence is claimed:
The Biomet Headless Compression and Twist-Off Screws are substantially equivalent to the currently marketed devices:

- DEPUY ORTHOPAEDICS, INC-K062352
- DEPUY ORTHOPAEDICS, INC-K971069
- LANDOS, INC-K962233
- WRIGHT MEDICAL TECHNOLOGY, INC- K082320
- MEMOMETAL TECHNOLOGIES- K070039

Device Description
The Biomet Headless Compression and Twist-Off Screws consist of bone screws of various lengths and diameters. The Biomet Headless Compression and Twist-Off Screws are also accompanied by dimensionally optimized corresponding instruments which are used to aid in the alignment and stabilization of fractures to the skeletal system. The Biomet Headless Compression Screws are a cannulated headless screw, which is inserted below the bone surface. The Biomet Headless Compression Screw is designed to minimize soft tissue irritation and provides compression due to a dual thread design. The Biomet Twist-Off Screw is a solid one piece screw that has a direct connection to a drill or large diameter pin driver, this allows the screw to break-off cleanly upon contact. The Biomet Twist-Off Screw also has compression capabilities with a thread-free segment that achieves compression at the osteotomy site.

Intended Use and Indications for Use

The Biomet Headless Compression Screws and Twist-Off Screws are indicated for fixation of bone fractures, fusion of a joint (arthrodesis) or bone reconstruction (osteotomy) of the mid-foot bones, metatarsal and phalanges of the foot or the phalanges, metacarpals and carpals of the hand. In the foot, these include procedures to correct Hallux Valgus (bunions), Hallux Varus and Hallux Rigidus, Hammer toe, Claw toe and Mallet toe.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The Intended Use for the Biomet Headless Compression and Twist-Off Screws is the same as the Intended Use cleared via K062352, K962233, and K971069 and are similar to K082320 and K070039.
- **Indications for Use:** The Indications for Use for the Biomet Headless Compression and Twist-Off Screws is similar and based on the Indications for Use cleared via K062352, K962233, and K971069 and are similar to K082320 and K070039.
- **Materials:** The Biomet Headless Compression and Twist-Off Screws are fabricated from Ti 6Al-4V. Titanium alloys are commonly used materials in orthopedic implants, and is a material that was used in predicate devices cleared via K062352, K962233, K971069, K082320, and K070039.
- **Design Features:** The design features of the Biomet Headless Compression and Twist-Off Screws are similar to the currently marketed devices K062352, K962233, K971069 K082320, and K070039. No issues of design differences have identified issues of safety or effectiveness.
- **Sterilization:** The Biomet Headless Compression and Twist-Off Screws will be offered in non-sterile and sterile by gamma irradiation. These sterilization configurations are similar to the predicate devices currently marketed via K062352, K962233, K971069, K082320, and K070039.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
    - Non-clinical performance testing and engineering justifications included mechanical tests per ASTM F543 that were performed to determine substantial equivalence of the Biomet Headless Compression and Twist-Off Screws including torsional, axial pullout and driving torque. Results indicate that the subject screws are substantially equivalent to legally marketed devices offering a reasonable assurance of safety and effectiveness.

- Clinical Tests
    - None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

The Biomet Headless Compression and Twist-Off Screws have been shown to be substantially equivalent to the predicate devices. Results of preclinical tests/engineering justification and the similarities with legal marketed predicated devices indicate the device will perform within the intended use and no new issues of safety or effectiveness have been raised.